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No. 01-740

In the Supreme Court of the United States

MYCOGEN PLANT SCIENCE, INC.
AND AGRIGENETICS, INC.,
Petitioners,

v.

MONSANTO COMPANY,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

JOHN F. LYNCH
Counsel of Record
SUSAN K. KNOLL
RICHARD L. STANLEY
HOWREY SIMON ARNOLD &
WHITE, L.L.P.
750 Bering Drive
Houston, Texas 77057
(713) 787-1400

Attorneys for Respondent
Monsanto Company

QUESTIONS PRESENTED

1) Whether the doctrine of prosecution history estoppel forecloses a patentee (Mycogen) from relying on the doctrine of equivalents to prove infringement of product claims that are limited to the exact synthetic gene disclosed in the '831 patent where Mycogen intentionally surrendered all broader patent claims to overcome prior art rejections during prosecution, including canceling claims that were too narrow to encompass Monsanto's accused gene?

2) Whether the Court of Appeals correctly held that there can be no infringement liability under 35 U.S.C. § 271(g) with respect to use or sale of products during the term of the asserted process patent, where such products could not have been "made by a process patented in the United States" at the time that the accused process was performed because the asserted United States process patent had not issued yet?

RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, respondent Monsanto Company ("Monsanto") states that Pharmacia Corporation is a publicly-traded corporation that currently owns more than 10% of Monsanto's stock. Respondent further states that all parties appear in the caption of the case on the cover page.

TABLE OF CONTENTS

QUESTIONS PRESENTED i

RULE 29.6 STATEMENT ii

OPINIONS BELOW 2

JURISDICTION 3

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED 3

STATEMENT OF THE CASE 4

A. Nature and Stage of the Proceedings 4

1. The District Court's Rulings 5

2. The Federal Circuit's Rulings 7

B. The Prosecution History Shows That Mycogen Canceled Product Claims That Were Too Narrow To Encompass Monsanto's Accused Gene 10

REASONS FOR DENYING THE PETITION 13

A. Mycogen Cannot Avoid Prosecution History Estoppel Simply Because Its Claims Limited To The Figure 1 Gene Were Not Narrowed 16

B. The Federal Circuit's Interpretation Of 35 U.S.C. § 271(g) Was Completely Correct 23

CONCLUSION 28

TABLE OF AUTHORITIES

Page(s)

CASES

Bio-Technology General Corp. v. Genentech, Inc.,
80 F.3d 1553 (Fed. Cir. 1996) 8, 25, 26

Exhibit Supply Co. v. Ace Patents Corp.,
315 U.S. 126 (1942) 13, 18, 21, 22

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000), *cert. granted*, No. 00-1543 (June 18, 2001) ..... *passim*

Genentech, Inc. v. Wellcome Found. Ltd.,
29 F.3d 1555 (Fed. Cir. 1994) 19

Gwaltney v. Chesapeake Bay Foundation,
484 U.S. 49 (1987) 24

Hoganas AB v. Dresser Indus., Inc.,
9 F.3d 948(Fed. Cir. 1993) 19

In re Amtorg Trading Corp.,
75 F.2d 826 (C.C.P.A. 1935) 26

Keystone Driller Co. v. Northwest Engineering Corp.,
294 U.S. 42 (1935) 18

Landreth Timber Co. v. Landreth,
471 U.S. 681 (1985) 23

Lemelson v. General Mills, Inc.,
968 F.2d 1202 (Fed. Cir. 1992) 19

Mark I Marketing Corp. v. R.R. Donnelly & Sons,
66 F.3d 285 (Fed. Cir. 1995) 16, 17

Mycogen Plant Science, Inc. v. Monsanto Co.,
61 F. Supp. 2d. 199 (D. Del. 1999), *aff'd*, 243
F.3d 1316 (Fed. Cir. 2001) 6, 7

RJR Nabisco, Inc. v. United States,
955 F.2d 1457 (11th Cir. 1992) 28

United States v. Mortons,
467 U.S. 822 (1984) 24

Wang Labs., Inc. v. Toshiba Corp.,
993 F.2d 858 (Fed. Cir. 1993) 19, 21

Warner-Jenkinson Co. v. Hilton Davis Chemical Co.,
520 U.S. 17 (1997) 18, 22

Zenith Labs., Inc. v. Bristol-Meyers Squibb Co.,
19 F.3d 1418 (Fed. Cir. 1994) 21

STATUTES

28 U.S.C. § 1254(1) 3

28 U.S.C. § 1292(b) 5

28 U.S.C. § 1295(a)(1) 3

28 U.S.C.§ 1338(a) 3

35 U.S.C. § 102(g) 6, 7

35 U.S.C. § 103 ..... 6, 7

35 U.S.C. § 112 ..... 6, 7

35 U.S.C. § 271(g).....*passim*

LEGISLATIVE REPORTS

H.R. Conf. Rep. No. 576, 100th Cong., 2d Sess. 1086 (1988) 28

H.R. Rep. No. 807, 96th Cong., 2d Sess. 19 (1986).....26

S. Rep. No. 83, 100th Cong., 1st Sess., Sec. III (1987) ...26, 27

S. Rep. No. 388, 100th Cong., 2d Sess. 33 (1988).....26

S. Rep. No. 663, 98th Cong., 2d Sess., Sec. IV (1984).....27

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BRIEF IN OPPOSITION

Respondent Monsanto Company respectfully urges the Court to deny the petition for a writ of certiorari to review the decision of the United States Court of Appeals for the Federal Circuit. While the doctrine of equivalents issue in this case was resolved by the Federal Circuit by applying its decision in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000), *cert. granted*, No. 00-1543 (June 18, 2001), the prosecution history estoppel and the noninfringement outcome are correct under "pre-*Festo*" law and thus are not dependent upon the Federal Circuit's "complete bar" rule announced in *Festo*.

Because Mycogen canceled claims that had been rejected over prior art but were themselves too narrow to cover Monsanto's accused gene, this petition can and should be denied no matter how this Court resolves the *Festo* case because Mycogen clearly surrendered the coverage that

would have been needed for the '831 patent to reach the accused products. Moreover, the Federal Circuit's decision construing 35 U.S.C. § 271(g) is clearly correct, and does not warrant review by this Court.

OPINIONS BELOW

The Federal Circuit's decision resolving the issues for which review is being sought is reported at 252 F.3d 1306 (Fed. Cir. 2001), and is reproduced at Petitioner's Appendix (Pet. App. 13a-38a). The relevant portions of that opinion addressing the two issues raised by the petition are found at Pet. App. 36a-38a (prosecution history estoppel), and at Pet. App. 32a-35a (interpretation of 35 U.S.C. § 271(g)). The Federal Circuit's supplemental opinion denying Mycogen's petition for rehearing on the prosecution history estoppel issue is reported at 261 F.3d 1345 (Fed. Cir. 2001), and is reproduced at Pet. App. 1a-12a.

The district court's decisions are not published. The district court's order of September 22, 1995 held that 35 U.S.C. § 271(g) did not apply to products made before the process patent in question issued, and is reproduced at Pet. App. 109a-119a. The district court's order of December 4, 1995 denied Mycogen's motion for reconsideration and interlocutory appeal of the earlier section 271(g) ruling, and is reproduced at Pet. App. 104a-108a. The district court's order of December 26, 1995 held that Mycogen was estopped from asserting infringement of its product claims 13 and 14 under the doctrine of equivalents, and is reproduced at Pet. App. 100a-103a.

The district court's order of April 8, 1996 denied Mycogen's motion for reconsideration of the prosecution history estoppel ruling and Mycogen's renewed motion for reconsideration of the § 271(g) ruling, and is reproduced at Pet. App. 98a-99a. The district court's order of August 15,

1996 included a denial of Mycogen's third motion for reconsideration of the § 271(g) ruling (that was styled as being a motion for summary judgment on the interpretation of 35 U.S.C. § 271(g)), and is reproduced at Pet. App. 91a-97a. The district court's order of November 10, 1999 that disposed of the remaining issues in the case does not relate to any issue raised by the petition, but is reproduced at Pet. App. 40a-90a.

JURISDICTION

The district court had jurisdiction under 28 U.S.C.§ 1338(a). The jurisdiction of the Court of Appeals was based on 28 U.S.C. § 1295(a)(1). The decision of the Court of Appeals denying rehearing of its May 30, 2001 decision was rendered on August 14, 2001. This Court has jurisdiction under 28 U.S.C. § 1254(1). The petition for certiorari was docketed on November 28, 2001. The time for filing this opposition was extended until January 15, 2002.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

With respect to the prosecution history estoppel and the doctrine of equivalents issue, there are no constitutional or statutory provisions to be interpreted in this case. As explained herein, the decision at issue involves a case-specific application of the doctrine of prosecution history estoppel, which is itself a limitation on the judicially-created doctrine of equivalents as may be applied in certain patent infringement cases.

The other issue presented by the petition concerns the proper construction of 35 U.S.C. 271(g), which provides:

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States

a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after –

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential compenent of another product.

STATEMENT OF THE CASE

A. Nature and Stage of the Proceedings

On May 23, 1995, Mycogen filed this case in the United States District Court for the Southern District of California asserting that Monsanto infringed Mycogen's U.S. Patent No. 5,380,831 ("the '831 patent") based upon the genes in certain of Monsanto's insect-resistant crops. Pet. App. 41a. The '831 patent contained 14 claims. Notably, claims 1-12 were "process" claims while claims 13-14 were "product" claims.

Claims 1-12 of the '831 patent were directed to a process of analyzing and modifying the native *Bacillus thurigiensis* ("*Bt*") gene to more closely resemble a plant gene with the goal of increasing its expression in plants. Figure 1 of the patent discloses the '831 patent's single example of a modified *Bt* gene, which includes hundreds of

changes to the nucleotide sequence present in the native *Bt* gene. Claims 13 and 14, the two product claims, are directed to the specific gene sequence illustrated in Figure 1 of the patent. Pet. App. 110a.

1. The District Court's Rulings

For purposes of determining whether Monsanto's accused activities could result in infringement liability under 35 U.S.C. § 271(g), the two relevant facts were undisputed. First, the parties agreed that the Monsanto products for which infringement damages were being sought by Mycogen were developed by Monsanto using a process performed before the '831 patent issued. Second, for purposes of the summary motion, Monsanto agreed that the process that it used before the '831 patent issued would be presumed to fall within the scope of one or more of Mycogen's later-issued process claims 1-12. Hence, Monsanto's motion for noninfringement under § 271(g) presented a pure issue of statutory construction to be resolved as a matter of law.

On September 22, 1995, the district court granted summary judgment for Monsanto that it could not infringe Mycogen's process claims (claims 1-12) under 35 U.S.C. § 271(g) with respect to any Monsanto genes had been designed and made before the '831 patent issued. Pet. App. 111a-115a. As noted, Mycogen immediately moved for reconsideration and to have the ruling certified for interlocutory appeal under 28 U.S.C. § 1292(b), but those motions were denied. Pet. App. 104a-108a (district court found no substantial ground for difference of opinion because "there is no credible argument to be made that section 271(g) applies to products manufactured outside the term of the process patent").

On December 26, 1995, the district court held that prosecution history estoppel prevented Monsanto's genes from infringing the two '831 product claims (claims 13-14) under the doctrine of equivalents because Mycogen had cancelled all product claims that were not limited to the exact DNA sequence shown in Figure 1 and because some of the cancelled claims were too narrow to cover Monsanto's accused gene.[1] Pet. App. 100a-103a. While those rulings disposed of most of Mycogen's infringement case, a final judgment could not be entered because Mycogen alleged that some infringement of process claims 1-12 had occurred after the '831 patent had issued.

On March 30, 1998, Monsanto filed two motions for summary judgment that claims 1-12 were invalid: one based upon 35 U.S.C. §§ 102(g) and 103 in light of Monsanto's prior invention, and one based upon 35 U.S.C. § 112 for lack of enablement. A1120-50; A1156-85. The former relied in part upon the collateral estoppel effect of the judgment in *Mycogen Plant Science, Inc. v. Monsanto Co.*, 61 F. Supp. 2d. 199 (D. Del. 1999), *aff'd*, 243 F.3d 1316 (Fed. Cir. 2001). In that case, the Delaware court upheld a jury verdict that two Monsanto scientists were prior inventors of the subject matter claimed in two related Mycogen patents based on the same inventive acts and specification as the '831 patent at issue here. *See* 61 F. Supp. 2d at 209-10; 235-42.

Because the Delaware trial on Mycogen's related patents was tried first, the California court stayed further proceedings in this case until the Delaware court resolved its post-trial JMOL and new trial motions. The Delaware court upheld that jury's invalidity verdict under § 102(g) and

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[1] Mycogen necessarily conceded the absence of literal infringement because Monsanto's gene differed more than 20% from the nucleotide sequence shown in Figure 1. Pet 11; Pet. App. 36a.

separately granted JMOL for Monsanto that the '600 and '862 patents were invalid for lack of enablement. 61 F. Supp. 2d at 257-60.

On November 10, 1999, the California district court lifted its stay and granted summary judgment that the two independent process claims in the '831 patent (claims 1 and 11) were invalid under 35 U.S.C. § 102(g) and that the dependent process claims were invalid under 35 U.S.C. § 103, based on Monsanto's accused genes being an earlier invention of the claimed subject matter by Monsanto. Pet. App. 50a-90a. The district court did not decide Monsanto's separate § 112 invalidity motion, holding that it was moot. Pet. App. 90a. Mycogen then appealed the final judgment to the Federal Circuit.

2. The Federal Circuit's Rulings

On May 30, 2001, the Federal Circuit affirmed that the Delaware judgment on the related Mycogen patents meant that Monsanto was the first to reduce the invention claimed in the '831 process claims to practice, but held that Monsanto had not established an absence of genuine issues of material fact over whether Mycogen had been the first to conceive and then diligently reduce the invention to practice. Pet. App. 17a-30a. Thus, the Federal Circuit reversed the summary judgment of invalidity under 35 U.S.C. § 102(g) and § 103, and remanded those issues to the district court.[2]

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[2] Upon remand, the district court ordered supplemental briefing on Monsanto's summary judgment motion that claims 1-12 were invalid under § 112 that was previously denied as moot. That briefing was completed on December 10, 2001. If that motion is granted, further proceedings with respect to the remanded invalidity issue of claims 1-12 under § 102(g) and with respect to the § 271(g) issue raised by Mycogen's petition would be unnecessary to the resolution of this case.

The Federal Circuit affirmed the district court's statutory construction ruling that Monsanto could not be liable under § 271(g), for infringement of claims 1-12 based on having performed its accused process before the '831 patent issued.

> We think Monsanto has the better of the argument based on the language of § 271(g). In the phrase "a product which is made by a process patented in the United States" the verbs "made" and "patented" are part of a parallel construction, which suggests that for infringement to be found the process must be patented at the time the product is made.

Pet. App. 34a. The Federal Circuit agreed that its decision in *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553 (Fed. Cir. 1996), did not address that question. Pet. App. 33a. Moreover, the Court of Appeals recognized that the purpose of § 271(g) had been to grant patent holders the same protection against foreign infringers that they had against domestic infringers, and there was no remedy accorded on a process patent against domestic entities that practice a process before a patent on that process issues. Pet. App. 34a-35a. Hence, the Federal Circuit affirmed that § 271(g) requires that "the patent be issued and in force at the time that the process is practiced and the product is made." Pet. App. 35a.

With respect to the district court's ruling that prosecution history estoppel foreclosed any infringement of claims 13 and 14 under the doctrine of equivalents, the Federal Circuit also affirmed. Pet. App. 36a-38a. The Court of Appeals recognized that the two product claims had not been amended. Pet. App. 37a. However, the Court discerned

no legally-significant difference between canceling a claim having a broad limitation and replacing it with a claim having a narrower limitation, and amending a claim to narrow a limitation. Pet. App. 37a-38a. Noting that this concept was not a new development under the doctrine of prosecution history estoppel, Pet. App. 38a, the Federal Circuit then applied its *Festo* decision to hold that Mycogen was entitled to no range of equivalents. *Id.*

Mycogen petitioned for rehearing on the prosecution history estoppel issue only, asserting that the Federal Circuit had apparently not understood the prosecution history of the '831 patent. Making arguments similar to those in its present petition, Mycogen asserted that its two product claims based on the Figure 1 sequence had been in its original application and were only amended to depend from a succession of broader claims (that were never allowed and eventually canceled). According to Mycogen, the two allowed claims had never themselves been narrowed, so the rationale of the Federal Circuit's *Festo* decision did not apply to foreclose the doctrine of equivalents.

Somewhat unusually, the Federal Circuit panel denied rehearing in a supplemental opinion which demonstrated that the panel fully understood Mycogen's prosecution history, despite having not recited it in detail in the original opinion. Pet. App. 1a-12a. As summarized therein:

> [T]he examiner in this case made clear that in light of the unpredictability of expression of synthetic genes, demonstration of enablement was required for allowance. The examiner also was clear that when only one synthetic gene was shown to be enabled, no broader claim scope was allowable. Faced with these rejections, Mycogen acquiesced in the

> examiner's proposal to cancel all claims except those specifically reciting the Figure 1 sequence. Thus, the prosecution history reveals that what the examiner ultimately proposed, and Mycogen accepted, was claim language limited to sequences taken from the preferred embodiment set forth in Figure 1. Under these circumstances, it is appropriate to limit Mycogen to the literal scope of the claims to which it agreed.

Pet. App. 11a-12a.

B. The Prosecution History Shows That Mycogen Canceled Product Claims That Were Too Narrow To Encompass Monsanto's Accused Gene

Mycogen concedes that the two product claims in the '831 patent literally cover only the specific nucleotide sequence pictured in Figure 1 of the patent. Pet. 7. Specifically, claim 13 is to a gene comprising nucleotides 1 through 1793 of the sequence shown in Figure 1, while claim 14 is to a gene comprising nucleotides 1 through 1833 of that sequence. *Id.* However, purportedly because the prosecution history of the '831 patent is too "complex" to be summarized any more than "briefly" in the petition, Mycogen's petition omits several key facts that are determinative of the prosecution history estoppel issue.

Mycogen's attack on the Federal Circuit's application of prosecution history estoppel under *Festo* is premised solely upon claims 13 and 14 not being the subject of a "narrowing" amendment during prosecution. *See, e.g.*, Petition, at 22-23. What Mycogen's petition conveniently fails to mention is that those two product claims could hardly have been the subject of a narrowing amendment because

they were already the narrowest possible product claims that could be in the application – limited specifically to two different DNA lengths of the "exact" nucleotide sequence shown in Figure 1.[3]

Throughout the prosecution of the '831 patent, the PTO refused to issue product claims broader than the precise DNA sequence of the Figure 1 gene. Pet. App. 9a, 11-12a. In all, Mycogen sought over 40 such claims. As the district court and the Federal Circuit explained, the PTO rejected every one as obvious over or as anticipated by prior art and as not enabled by Mycogen's specification. Pet. App. 101a-102a; Pet. App. 3a-9a. Mycogen eventually canceled all such broader product claims to obtain the '831 patent. Pet. App. 11a-12a.

It cannot be disputed that some of the claims sought and ultimately canceled by Mycogen to overcome prior art rejections were too narrow to encompass Monsanto's accused gene.[4] For example, Mycogen's prosecution claim 2 was directed to a synthetic gene having a DNA sequence "at least about 85% homologous to a native insecticidal protein gene of *Btt.*" Pet. App. 101a-102a. In contrast, Monsanto's

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[3] The gene in Figure 1 of the '831 patent is a synthetic *Bt* gene that differs from the corresponding native *Bt* gene in about 11% of the nucleotides. *See* Kemp/Sutton Declaration (Table 1). Moreover, the '831 patent states that the synthetic gene is preferably "at least approximately 85% homologous to an insecticidal protein gene of *Bt*," *i.e.*, that the synthetic gene be no more than 15% different than the native gene.

[4] Monsanto's *Bt* gene accused under claims 13 and 14 is the gene in Monsanto's NewLeaf® potato, which has changes to about 22% of the nucleotides of the native *Bt* gene. Kemp/Sutton Declaration (Table 1). There is also a difference of about 21% between Monsanto's accused gene and the Figure 1 gene. *Id.* Thus, Monsanto's accused gene is outside the preferred 15% range in the '831 patent and is more different from the Figure 1 gene than the Figure 1 gene is from the native *Bt* gene.

accused gene has less than 78% homology with the native *Bt* gene and thus was literally outside the scope of canceled prosecution claim 2. *See supra* note 4.

Similarly, Mycogen's canceled prosecution claims 5-6 required that the overall frequency of preferred codon usage be within about 75% or 90% of the frequency of codon usage preferred in plants, as shown in Table 1 of the '831 patent specification. Pet. App. 37a. Those canceled claims would also have been too narrow to cover Monsanto. Monsanto's accused gene has a frequency of preferred codon usage of only 51%, which is much lower than the minimum 75% in prosecution claims 5-6. *See* Fischhoff Declaration (¶ 17).

Mycogen then rewrote prosecution claim 1 but the PTO again rejected it, as well as prosecution claims 2 and 5-6, based upon prior art and a lack of enablement. Pet. App. 3a-4a; 36-37a. Mycogen re-filed its patent application, added new prosecution claim 31, and changed the dependency of prosecution claims 2-6 to new claim 31. Pet. App. 4a-5a. The Examiner again rejected prosecution claims 1-2, 5-6, and 31 as not enabled and as unpatentable over prior art. Pet. App. 5a.

Mycogen then canceled claim 31 and substituted prosecution claim 35, again changing the dependency of prosecution claims 2-6. Pet. App. 5a-6a. Claims 35, 2, and 5-6 were again rejected as not enabled and as unpatentable over prior art. Pet. App. 6a. Mycogen re-filed a second time. Pet. App. 7a-8a. Mycogen finally gave in and canceled all product claims that were not limited to the Figure 1 gene, stating that amendment "obviates the rejections which have been raised throughout the prosecution history of this application." Thus, the only product claims that Mycogen obtained in the '831 patent were limited to the exact sequence shown in Figure 1. Pet. App. 9a, 11a-12a.

REASONS FOR DENYING THE PETITION

Mycogen's petition is premised on the position that the so-called "complete bar" to the doctrine of equivalents arising from application of prosecution history estoppel under the Federal Circuit's decision in *Festo was* erroneously invoked against claims 13 and 14 by the Federal Circuit because those claims were never the subject of any narrowing amendment. Pet. at 5. However, Mycogen's petition merely attempts to further prolong Mycogen's baseless infringement assertions on claims 13 and 14 in light of this Court's decision to review the merits of the Federal Circuit's *Festo* decision.

The district court's summary judgment ruling that there could be no infringement of claims 13 and 14 under the doctrine of equivalents due to prosecution history estoppel was rendered in December 1995 -- almost five full years before the Federal Circuit's *Festo* decision. Mycogen's appeal to the Federal Circuit was fully briefed and argued before *Festo* issued. While the Federal Circuit cloaked its affirmance of the district court in the language of *Festo*, that decision did not create a new reason why Mycogen is legally unable to show infringement of claims 13 and 14 – it is because Mycogen clearly relinquished the claim scope necessary to cover Monsanto's accused gene when it canceled rejected claims that were too narrow to cover Monsanto in order to obtain the '831 patent. The rule that such a surrender of subject matter gives rise to an estoppel has been the law since long before *Festo*. *See Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136-37 (1942) (and cases cited).

Claims 13 and 14, the only product claims in the '831 patent, were admitted by Mycogen during prosecution to be directed to the "exact" nucleotide sequence of the gene

disclosed in Figure 1 of the patent. Throughout six-plus years of prosecution before the PTO, Mycogen repeatedly attempted to obtain over 40 product claims of varying scope that were not limited to the exact sequence of Figure 1. The PTO repeated rejected all such claims on both prior art and nonenablement grounds. Eventually, Mycogen agreed to cancel all other product claims to obtain allowance of claims 13 and 14. Included among those canceled product claims were claims that were themselves too narrow to literally encompass the Monsanto gene accused of infringing those two product claims.

Based on those indisputable facts, the district court properly held under "pre-*Festo*" law that the only subject matter that Mycogen could have possibly recaptured by applying the doctrine of equivalents to claims 13 and 14 is that which falls between the scope of the rejected prosecution claims 2, 5 and 6 surrendered by Mycogen and the scope of the two product claims specific to the Figure 1 gene allowed by the PTO. Pet. App. 101a-102a. Because Monsanto's accused gene did not fall within Mycogen's potential range of recapture of claim coverage, there could be no infringement of the '831 product claims by Monsanto as a matter of law – even before *Festo*.

Correctly holding that prosecution history estoppel clearly attached in this case, the Federal Circuit *sua sponte* applied its *Festo* decision to hold that Mycogen could not recapture any genes beyond the literal scope of claims 13 and 14. Pet. App. 37a-38a; 2a-12a. However, the only practical significance of the decision to invoke *Festo* was that the Federal Circuit could decide that Mycogen was entitled to no range of equivalents at all before reaching the district court's equally-valid conclusion that any possible range of equivalents could not have been broad enough to encompass Monsanto's gene anyway. Either way, the inescapable legal

conclusion is that prosecution history estoppel bars any claim by Mycogen for alleged infringement of claims 13 and 14 under the doctrine of equivalents.

Regardless of whether this Court affirms, narrows, or reverses *Festo*, the doctrine of prosecution history estoppel as consistently applied by this Court and by every pre- and post-*Festo* decision of the Federal Circuit provides no basis for altering the conclusion that claims 13 and 14 cannot be infringed as a matter of law. Hence, this Court should reject Mycogen's suggestion that its petition must be granted and the case remanded to the Federal Circuit unless this Court affirms *Festo* entirely because the result in this case cannot possibly change in light of Mycogen's clear surrender of the very subject matter needed to encompass Monsanto's accused gene.

Finally, with respect to Mycogen's other question presented, the Federal Circuit's legal analysis and statutory construction of 35 U.S.C. § 271(g) is entirely correct, and thus presents no reason for this Court to review that aspect of the Court of Appeals' decision. Under the plain language of the statute, none of the commercial genes made using Monsanto's accused process before the '831 patent issued can infringe the '831 process claims under § 271(g) because those genes are not products "made by a process patented in the United States" as required by the statute. As properly interpreted by both lower courts in this case, §271(g) simply does not apply to create infringement liability for the use or sale of products made *before* a claimed process was later patented in the United States.

A. Mycogen Cannot Avoid Prosecution History Estoppel Simply Because Its Claims Limited To The Figure 1 Gene Were Not Narrowed

Mycogen's petition fails to acknowledge that every product claim that Mycogen introduced during prosecution that was broader than the "exact" gene in Figure 1 was rejected on prior art and enablement grounds, and each such claim was eventually canceled by Mycogen in order to allow claims 13 and 14 to issue in the '831 patent. Pet. App. 3a-12a. More importantly, several of Mycogen's rejected and later-canceled claims were too narrow to encompass Monsanto's accused gene – which is exactly why prosecution history estoppel has always prevented the doctrine of equivalents from being used to allow the asserted patent to encompass such surrendered subject matter.

Monsanto's position can be easily demonstrated by focusing on Mycogen's canceled prosecution claims 2, 5, and 6. Those cancellations -- at a minimum – properly foreclosed Mycogen from claiming a potential range of equivalents for prosecution claims 3 and 4 (issued as claims 13 and 14) which was outside the range falling between the canceled claims and the issued claims.

Mycogen's assertion that the cancellation of claims 2, 5, and 6 did not amount to a narrowing of the subject matter that could possibly be covered by the issued '831 product claims because those claims were not themselves amended or because claims 3 and 4 did not depend from claims 2, 5, and 6 is linguistic nonsense.[5] As the Federal Circuit correctly

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[5] The fact that Mycogen's two product claims were later rewritten in independent form does not alter the fact that each is limited to the gene shown in Figure 1 of the '831 patent. In any event, the amendment of those claims to independent form is not the basis on which the district court's or the Federal Circuit's estoppel decision was based. *See Mark I*

recognized, the cancellation of claims 2, 5, and 6 resulted in prosecution history estoppel affecting prosecution claims 3 and 4 just as if those claims had been directly amended to achieve their current form.

Using Mycogen's canceled prosecution claim 2 as a specific example, the Federal Circuit was correctly in stating that there is no substantive difference between (1) amending a rejected claim directed to a gene that is 85% homologous to the native gene so that it becomes limited to the specific gene shown in Figure 1 and (2) canceling a rejected claim directed to a gene that is 85% homologous to the native gene so that the only pending claim left in the application is limited to the specific gene shown in Figure 1. Pet. App. 37a-38a. As a matter of logic, there can be no difference for purposes of the rules announced in *Festo*. It should not matter for purposes of a patent owner's ultimate right to exclude whether the applicant begins by filing a set of progressively narrower claims and is only able to obtain the narrowest after canceling the rest in the face of PTO rejections, or whether the applicant begins with one broad claim and successively narrows it after a series of PTO rejections until its contents end up being the same as the narrowest one allowed in the former situation.

If Mycogen wanted to obtain additional coverage in the '831 patent beyond that signified by the claims directed

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Marketing Corp. v. R.R. Donnelly & Sons, 66 F.3d 285, 292 (Fed. Cir. 1995) (that particular claims were not themselves rejected or amended does not foreclose application of prosecution history estoppel). Moreover, the term "comprising" in the two issued product claims does not avoid the requirement that every specified nucleotide in Figure 1 must be present in any accused gene, regardless of what other elements may be present.

to exact gene in Figure 1, it could have either appealed the rejections or amended the rejected claims to a narrower scope (such as having at least about 95% homology with the native gene) and convinced the PTO that such narrower claim should be allowed. Of course, if Mycogen had done the latter, no further range of equivalents would be allowed under *Festo*. Having not done so, the Federal Circuit properly applied the rationale of *Festo* to limit Mycogen from using the doctrine of equivalents to recapture any subject matter beyond what is literally covered by the gene in Figure 1 because Mycogen elected not to seek it from the PTO before allowing the '831 patent to issue.

In that regard, *Festo* announced no new law nor altered any old law. In *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 30 (1997), this Court recently described prosecution history estoppel as being "a well-established limit on nonliteral infringement." Moreover, this Court explained that prosecution history estoppel most clearly arose when an applicant overcame a PTO rejection based on prior art by narrowing the scope of the original claim and effectively disavowing coverage of subject matter excluded by the amendment. *Id.* at 31 (citing *Exhibit Supply*, 315 U.S. at 136, and *Keystone Driller Co. v. Northwest Engineering Corp.*, 294 U.S. 42, 48 & n.5 (1935)); *see also* 520 U.S. at 31 n.5 (and other cases cited).

Long before *Festo*, the Federal Circuit also had consistently held that the doctrine of equivalents was not to be used as a tool for expanding the protection of a patent after the examination has been completed.

> An applicant should not be able deliberately to narrow the scope of examination to avoid during prosecution scrutiny by the PTO of subject matter with the objective of more

> quickly obtaining a patent (or avoiding the risk of an estoppel), and then obtain in court, either literally or under the doctrine of equivalents, a scope of protection which encompasses that subject matter.

Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555, 1564 (Fed. Cir. 1994); *see Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 951-52 (Fed. Cir. 1993) ("The essence of prosecution history estoppel is that a patentee should not be able to obtain, through the doctrine of equivalents, coverage of subject matter that was relinquished during prosecution to procure issuance of the patent").[6]

The focus of a prosecution history estoppel analysis is on what subject matter was surrendered, not on how the claims may have been numbered before their cancellation. Given the clear substantive overlap between the subject matter of Mycogen's original application claims 3 and 4 and canceled claims 2, 5, and 6, Mycogen's suggestion that the Federal Circuit and the district court erred in relying on the relationship between the subject matter of those claims absent direct dependency between them can only be rejected. Thus, given Mycogen's demonstrated inability to get any other product claims allowed over the prior art coupled with Mycogen's express surrender of rejected product claims that were already too narrow to encompass Monsanto's accused

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[6] *See also Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 868 (Fed. Cir. 1993) ("A patent attorney should not be able, however, to choose one course of action within the PTO with the anticipation that, if later checked, he or she can always choose an alternative course of prosecution in a trial before a federal judge."); *Lemelson v. General Mills, Inc.*, 968 F.2d 1202, 1208 (Fed. Cir. 1992) (a patentee "cannot acquiesce to a rejection and to an agreed alternative, and now ... shift his stance 180° to argue for a second bite at the abandoned apple").

gene, the basis for prosecution history estoppel in this case is unmistakable under either pre- or post-*Festo* law.

The Federal Circuit properly held that Mycogen's contrary arguments indeed were placing form over substance. *See* Pet. App. 38a. The same is true of Mycogen's attack on the Federal Circuit's application of *Festo*. Mycogen's petition is directed more toward theoretical problems with *Festo* than on the Federal Circuit's application of *Festo*'s rationale to the present facts. *See* Pet. 20-21 (complaining that a "copyist" might be able to avoid infringing a gene claim by changing a single nucleotide, but then conceding that Monsanto's accused gene in this case had more than a one-nucleotide difference). As noted above, Monsanto's gene contains about 22% changes from the native gene, which is both outside the preferred range set forth in the patent as well as outside the range specified in proposed product claims rejected over prior art that were later canceled by Mycogen during prosecution.

Festo did not alter the prior precedent of this Court and of the Federal Circuit mandating the legal effect of relinquishing subject matter during prosecution, which was correctly followed by the district court in rendering its judgment of noninfringement. While Mycogen apparently assumes that this case must be remanded to the Federal Circuit if *Festo* is reversed or at all modified, Pet. 17, it is respectfully submitted that such a remand would be a waste of judicial resources. Whether evaluated under *Festo* itself or under "pre-*Festo*" law, Mycogen unambiguously surrendered the claim scope that would be needed to enable Mycogen to encompass Monsanto's accused gene under the doctrine of equivalents.

By cutting off a patentee's ability to recapture subject matter surrendered, the doctrine of prosecution history

estoppel thereby avoids making a court to indulge in speculative inquiry as to whether the patentee actually gave up too much. *Exhibit Supply*, 315 U.S. at 136 *see Wang Labs*, 993 F.2d at 868 (estoppel applies even though the patentee could have chosen a different or narrower basis for distinguishing the prior art cited by the PTO). Under *Festo*, there is no need to determine what was in fact surrendered because no range of equivalents is allowed once claim scope has been narrowed. 234 F.3d at 569-78. However, whether or not that absolute rule from *Festo* is retained, Mycogen cannot be allowed to use the doctrine of equivalents to inflate the exceedingly narrow product claims of the '831 patent to a scope previously relinquished.

A reasonable competitor reading the prosecution history of the '831 patent must be entitled to rely upon Mycogen's surrender of product claims that are too narrow to encompass such competitor's product. *Zenith Labs., Inc. v. Bristol-Meyers Squibb Co.*, 19 F.3d 1418, 1424 (Fed. Cir. 1994. Here, Mycogen canceled all such product claims -- after they had been rejected by the Patent Office for both prior art and enablement reasons -- in order to allow the '831 patent to issue. On that basis alone, prosecution history estoppel clearly must bar any possible infringement of claims 13 and 14 under the doctrine of equivalents in this case – as a matter of law.

Finally, Mycogen's alternative argument (Pet. 21-24) as to why this Court should still grant certiorari in this case even if this Court affirms the Federal Circuit's decision in *Festo* should be rejected. That makes no sense. If the narrowest claim in the application is made dependent upon a series of broader claims that are repeated rejected over prior art, the applicant cannot be allowed to avoid the resulting prosecution history estoppel limitation on the doctrine of equivalents by acquiescing in the rejections, canceling all

broader claims, and then asserting that the narrowest claim is infringed under the doctrine of equivalents by something that clearly falls outside the scope of the proposed application claims that were rejected and canceled.

Under Mycogen's apparent theory, a patentee can avoid be foreclosed in any manner by prosecution history estoppel as long as the original application contains the narrowest possible patentable claim that can be allowed without amendment, even if all other broader claims are continually rejected and never allowed. That turns the traditional doctrine of prosecution history estoppel completely on its head, and exposes Mycogen's petition as nothing more than an attempt to exploit any uncertainty over the Federal Circuit's *Festo* decision. If anything is certain about that decision, it clearly expanded the circumstances allowing prosecution history estoppel to bar reliance on the doctrine of equivalents. If Mycogen could not prevail as a matter of law before *Festo* was announced (as the district court correctly held), then Mycogen has no basis on which it could possibly prevail should *Festo* be affirmed.

For the reasons set forth above, this Court should deny certiorari in this case regardless of the outcome of its review of *Festo*. Indeed, unless this Court were to overrule its own precedents in *Warner-Jenkinson* and *Exhibit Supply* by abolishing the doctrine of prosecution history estoppel entirely (an issue not presented by *Festo*), Mycogen's petition can and should be denied before this Court even issues its *Festo* decision because nothing in either the Federal Circuit's *Festo* decision or rationale created a new basis for applying prosecution history estoppel in this case that did not exist under pre-*Festo* law.

B. The Federal Circuit's Interpretation Of 35 U.S.C. § 271(g) Was Completely Correct

It is undisputed that Monsanto's accused insect-resistant genes were designed and made before the '831 patent issued in 1995. Pet. 6 n.2. Nevertheless, Mycogen asserted that Monsanto's post-issuance use, sale, or offer for sale of products containing Monsanto's genes – genes that were made using what was at that time an unpatented process – infringes those process claims under 35 U.S.C. § 271(g). As the district court recognized when rejecting Mycogen's statutory interpretation (four times), and as properly affirmed by the Federal Circuit, Mycogen's position is at odds with the plain language and purpose of § 271(g).

"The starting point of every case involving the construction of a statute is the language itself." *Landreth Timber Co. v. Landreth*, 471 U.S. 681, 683 (1985). Section 271(g) states:

> Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States, a product which *is made by a process patented in the United States* shall be liable as an infringer, *if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent.* (emphases added.)

Thus, the determinative issue is whether a product of a process allegedly covered by the '831 process claims must have been made at a time when the process was actually "a process patented in the United States" (*i.e.*, after the U.S. patent covering the process issued). Monsanto's position is straightforward: before the '831 process claims issued, the Monsanto genes were made by a process *not* patented in the United States, so § 271(g) cannot and does not impose any

infringement liability for subsequent acts involving such products, whether during the term of the later-issued process patent or not.

Mycogen's interpretation below was based on the false premise that the last phrase of § 271(g) contains the only requirement for liability. According to Mycogen, because "making" is not a listed act, Congress did not require the act of manufacture using the patented process to take place during the patent term. Contrary to Mycogen's premise, however, "when" a process is used has a great impact on liability under § 271(g).

A court must read the statute as a whole. *United States v. Mortons*, 467 U.S. 822, 828 (1984). When read as a whole, § 271(g) imposes three distinct conditions for infringement liability. First, a product must be "made by a process patented in the United States." Second, the product must be imported into, offered for sale, sold or used in the United States (which was assumed here). Third, those acts must take place during the term of the process patent in question. Mycogen ignores the first condition, and misconstrues the third.

The past tense terms "made" and "patented" in the clause "made by a process patented in the United States" confirms that Congress intended it to have temporal significance in that the process being protected already be the subject of an issued U.S. patent. *See Gwaltney v. Chesapeake Bay Foundation*, 484 U.S. 49, 57-63 & n.4 (1987) (tense used in a statute is significant). By giving meaning to all the phrases, not just the last one isolated by Mycogen, the Federal Circuit and the district court correctly held that no liability can attach to Monsanto's products made before the process was patented in the United States because

the process used was not "patented" when the product was "made." Pet. App. 34-35a.

Despite its mischaracterization of *Bio-Technology Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553 (Fed. Cir. 1996), being expressly rejected by the very court that authored the opinion, Pet. App. 33a, Mycogen continues to assert that a conflict exists between that decision and this one. However, *Bio-Technology* does not support Mycogen's attempt to ignore the express statutory language of § 271(g). There, Genentech sought to enjoin importation of an artificial hormone produced using a process covered by two U.S. patents. One covered a process for constructing a plasmid, which, when introduced into a microbial organism, caused the hormone to be produced. 80 F.3d at 1557. Bio-Technology constructed the plasmid once, in Israel, in 1983. Notably, Genentech's patent issued in 1982, before § 271(g) was effective. 80 F.3d at 1562.

Bio-Technology argued that it was improper to apply § 271(g) retroactively to conduct that was not an infringement at the time. 80 F.3d at 1562. The Federal Circuit disagreed, holding that the infringement "does not consist of the making of a product patented in the United States; it is the importation, offer to sell, sale, or use of a product made by such process that infringes." *Id.* Actually, however, liability under § 271(g) requires all three statutory conditions described above to be met, which was clearly the situation in *Bio-Technology*.

Mycogen's attempt to forcefit *Bio-Technology* to this case misses a critical distinction. In *Bio-Technology*, the process used in 1983 to construct the plasmid was "patented in the United States" at that time. Even though § 271(g) was not effective, this Court held that the subsequent importation of a product "made by such process" during the term of the

patent came within § 271(g). 80 F.3d at 1560. However, that ruling cannot extend Mycogen's process patent rights to the period before its process was patented. Unlike in *Bio-Technology*, Mycogen had no United States process patent to enforce at the time of Monsanto's use. Thus, Mycogen cannot invoke § 271(g) now.

Mycogen's interpretation would revise § 271(g) to encompass products made by a process which "subsequently" or "eventually" becomes "patented in the United States." As the Federal Circuit held, nothing in § 271(g) altered the fundamental rule that a U.S. patent can only be infringed during the term of the patent. Pet. App. 35a; *see In re Amtorg Trading Corp.*, 75 F.2d 826, 831-32 (C.C.P.A. 1935). Section 271(g) merely provides a remedy for acts that would have been infringements of a U.S. process patent but for the fact that the process was being performed outside the United States. *See* S. Rep. No. 83, 100th Cong., 1st Sess. 46 (1987). However, completion of a process before a patent issued on that process has never been an act of infringement, no matter where it was performed. That rule was not altered by § 271(g).

Mycogen's attempt to impose liability for the completion of a process before a United States patent issues on that process is also wholly inconsistent with the statute's legislative intent. The dominant purpose underlying § 271(g) was to prevent manufacturers from having the unfettered ability to copy a process from an issued U.S. patent, to use that process in another country to make unpatented products, and then import, use, or sell those products in the United States in competition with the U.S. process patent holder. *E.g.*, H.R. Rep. No. 807, 96th Cong., 2d Sess. 19 (1986)). The legislative history unmistakably reveals that Congress was acting to eliminate that loophole in U.S. law. *See* S. Rep. No. 388, 100th Cong., 2d Sess. 33 (1988) ("Current

patent [illegible] does not reach the foreign pirating of American innovations when the products are manufactured abroad and then shipped back to the United States."). Clearly, the problem being remedied, copying U.S. process patents for use overseas, could only arise after a U.S. patent had issued.

Early versions of the bills that ultimately resulted in § 271(g) limited the scope of the added protection to the importation, use or sale of products "made in another country" by such processes. Because the United States could not discriminate against foreign companies under its GATT obligations, all bills proposed after 1984 provided only that importation, use, and sale of products made by processes patented in the United States would be infringements; *i.e.*, regardless of where the products were made. *See* S. Rep. No. 663, 98th Cong., 2d Sess., sec. IV, at 5 (1984) (broader language adopted "to avoid any appearance of discrimination against foreign manufacturers"). However, Congress concluded that giving an infringement remedy with respect to the use or sale of a product made in the United States would have little practical significance because the patentee already had an existing remedy for process patent infringement directly against the domestic manufacturer. *See, e.g.*, S. Rep. No. 83, 100th Cong., 1st Sess., Sec. III, at 44 (1987).

A U.S. process patent owner did ***not*** have an existing remedy against use of a process in the United States ***before*** the patent issued. Nothing in the legislative history indicates that Congress intended or understood that it would be changing the law to allow infringement liability to attach to products made by practicing an unpatented process in the United States before the patent on that process issued. Such a significant change to U.S. law cannot be presumed to have been done by Congress unwittingly or in utter silence.

H.R. Conf. Rep. No. 576, 100th Cong., 2d Sess. 1086 (1988), stated that the House and Senate bills agree that "using, selling or importing a product *made in violation of a U.S. process patent* is an act of infringement." A6193 (emphasis added). *See RJR Nabisco, Inc. v. United States,* 955 F.2d 1457, 1462 (11th Cir. 1992) (a conference committee report is the legislative history accorded the greatest deference by courts). Because a patent cannot be "violated" before it issues, that report confirms that Congress contemplated that only post-issuance uses would be implicated by § 271(g).

Based on the above, the Federal Circuit concluded that the process claims 1-12 cannot be infringed by the Monsanto commercial *Bt* genes made before the '831 patent issued. There is no reason for this Court to undertake to review that entirely correct decision.

CONCLUSION

The petition for a writ of certiorari should be denied in its entirety.

Respectfully submitted.

JOHN F. LYNCH
Counsel of Record
SUSAN K. KNOLL
RICHARD L. STANLEY
HOWREY SIMON ARNOLD & WHITE, L.L.P.
750 Bering Drive
Houston, Texas 77057
(713) 787-1400

Counsel for Respondent Monsanto Company

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